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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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German Spangenberg

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

10/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,857	Applicant(s) SPANGENBERG ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-73 and 75-82 is/are pending in the application.
- 4a) Of the above claim(s) 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-73, 75-77 and 79-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1638

DETAILED ACTION

1. Claims 65-73 and 75-82 are pending.
2. In the response filed 13 October 2009, Applicant elected group II (SEQ ID NOs:2 and 10 and optionally SEQ ID NO:14). As claim 78 is drawn to a nonelected invention, it is withdrawn from consideration.
3. The claims contain sequences drawn to an invention nonelected with traverse in the response filed 13 October 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
4. The rejection of claims 65 and 67 under 35 U.S.C. 102(b) as being anticipated by Suzuki et al (2000, Mol. Breed. 6:239-246) is withdrawn in light of Applicant's amendment of the claims.
5. The rejection of claims 62-76 under 35 U.S.C. 103(a) as being unpatentable over Spangenberg et al (US Patent Application Publication 2005/0069884, filed 4 October 2002) is withdrawn in light of Applicant's representative statement under 103(c).
6. The rejection of claims 62-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon et al (US Patent Application Publication 2004/0093632, filed 28 June 2002) in view of Arioli et al (1994, Gene 138:79-86) withdrawn in light of Applicant's arguments.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1638

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 65-73, 75-77, 79-80 and 82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Due to Applicant's amendment of the claims, the rejection is modified from the rejection set forth in the Office action mailed 18 February 2010, as applied to claims 62-76. Applicant's arguments filed 18 August 2010 have been fully considered but they are not persuasive.

The essential features of the claims are constructs comprising antisense to a nucleic acid encoding SEQ ID NOs:2, 4, 6, or 8, antisense to a nucleic acid encoding SEQ ID NO:10, and, optionally, antisense to a nucleic acid encoding SEQ ID NOs:12, 14 or 16, "functionally active fragments" of those nucleic acids, and variants have at least 90% identity to any of these sequences, wherein the sequences modify the levels of chalone synthase, dihydroflavonal 4-reductase and leucoanthocyanidine reductase in a plant cell. SEQ ID NO:2, 10 and 14 are the elected sequences.

The structural features that distinguish those nucleic acids that modify the levels of chalone synthase, dihydroflavonal 4-reductase and leucoanthocyanidine reductase in a plant cell from those that do not are not described in the specification.

Hence, Applicant has not, in fact, described the constructs the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Art Unit: 1638

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, Applicant does not appear to have been in possession of the claimed genus at the time this application was filed.

Applicant urges that pg 5-6 of the specification discuss conservative substitutions and provides an alignment of sequences (response pg).

This is not found persuasive. Applicant's response, in combination with the specification provides no definition of TrCHS3as, TrCHS3cs, TrCHS3fs, TrCHS3hs, TrCHS3ap, TrCHS3cp, TrCHS3fp, TrCHS3hp, TrLARas, TrLARbs, TrLARcsTrLARap, TrLARbp, and TrLARcp in Appendix A; thus, the Appendix could not be considered.

The paragraph spanning pg 5-6 defines “functionally active” fragments and variants as those that modify flavonoid biosyntheses in a plant and indicates that they can have modification and/or a certain percent identity. Conservative amino acid substitutions are provided as an example of such a modification. This paragraph in the specification does not describe the structural features of those nucleic acids that modify the levels of chalcone synthase, dihydroflavonol 4-reductase and leucoanthocyanidine reductase in a plant cell; it merely defines the desired outcome, as not all fragments or variants with 90% identity or those with only conservative substitutions, will have the desired function.

See *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 94 USPQ2d 1161 (Fed. Cir. 2010) at pg 1171:

For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus...

Art Unit: 1638

[M]erely drawing a fence around the outer limits of purposed genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 65-73, 75-77 and 79-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 18 February 2010, as applied to claims 62-76. Applicant's arguments filed 18 August 2010 have been fully considered but they are not persuasive.

Claims 62, 65, 70 and 77 are indefinite in their recitation of "dihydroflavonal 4-reductase (BAN)" as not all BAN proteins are dihydroflavonal 4-reductases (Dixon et al (US Patent Application Publication 2004/0093632, ¶206). Does Applicant mean only those dihydroflavonal 4-reductases that are encoded by a BAN gene?

Applicant urges that anthocyanidin reductase is the name now given the BAN homolog in *T. repens* and TrLAR (leucoanthocyanidine 4-reductase) is another gene; at the time of filing BAN was thought to be DFR-like (response pg 12).

This is not found persuasive. As it appears from Applicants response, the instantly claimed DFR is not now considered BAN, it is suggested that this abbreviation be replaced with --DFR--.

Applicant's amendments have overcome the other rejections under 35 U.S.C. 112, second paragraph.

Art Unit: 1638

11. Claim 81 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 21, 2010

/Anne R Kubelik/

Primary Examiner, Art Unit 1638